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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,038	11/17/2000	Carlos Vonderwalde Freidberg	24079-1071	7272

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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/716,038	FREIDBERG, CARLOS VONDERWALDE	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,29,30,32,35-38,41-46,48 and 49* is/are pending in the application.

4a) Of the above claim(s) *10-20,32 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,29,30,35-38,41-45,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Claims 10-20, 32, and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Claim Objections

Claims 1-9, 29, 30, 35-38, 41-45, 48, and 49 are objected to because of the following informalities: In base claim 1, on line 4 and in base claim 29, on line 7, the range of "less than 0.45 mm" lacks clear antecedent basis from the specification that only discloses "less than 0.25 mm" and a range of "about 0.25 mm to about 0.75 mm, with an average of about 0.45 mm"; see page 9 of the specification and see 37 CFR 1.75(d)(1). The Examiner queries whether Applicants intended to claim the range of "less than 0.25 mm" instead. The other claims are dependent upon these base claims and thus they have the same objectionable language. Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In base claim 1, on line 4 and in base claim 29, on line 7, the range of "less than 0.45 mm" lacks clear antecedent basis from the specification that only discloses "less than 0.25 mm" and a range of "about 0.25 mm to about 0.75 mm, with an average of about 0.45 mm"; see page 9 of the specification and see 37 CFR 1.75(d)(1). The other claims are dependent upon these base claims and thus they have the same objectionable language.

Rejections Based Upon Prior Art

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-9, 29, 30, 36, 37, 38, 41-45, and 48-49 rejected under 35 U.S.C. 102(b) as anticipated by Love (97/24081) or, in the alternative, under 35 U.S.C. 103(a) as being unpatentable over Love (97/24081) as evidenced by Applicants' admission or Claeson et al (US 6,468,313) in view of Winston et al (US 6,117,166). Love (WO) discloses a tubular support frame made of expandable material (spring steel or Nitinol, see page 10, lines 21-27) which is wrapped with pericardial tissue or similar tissues; see page 4, lines 12-29, page 5, lines 7-33, and page 9, lines 26-29. The tissue is impervious because it is impervious to blood; see page 4, lines 25-29. It is inherently "relatively impervious so as to prevent tissue buildup and migration of smooth muscle cells" because it is arguably the same tissue as that disclosed and claimed by Applicants. Furthermore, "thinned" is treated as a product-by-process limitation does not clearly result in a different product from pericardial tissue that has not been thinned; see MPEP 2113 that is incorporated herein by reference.

With regard to the thickness limitation of "heterologous tissue less than 0.45 mm thick", Love as evidenced by Applicants' admission or Claeson teaches that heterologous pericardial tissue is inherently within the claimed range; see Applicants'

admission on page 9, lines 6-9 where it is disclosed that bovine or heterologous pericardium was commercially available in the claimed thickness range. Claeson teaches that the claimed thickness for bovine pericardial tissue was known to be 0.2 to 0.8 mm in thickness; see column 3, lines 63-67 and column 10, lines 1-9. Love teaches using heterologous pericardial tissue for the tissue thereof.

Alternatively, it is not explicitly clear that Love discloses an identical product to that claimed or one that is substantially identical due to the limitation requiring a "thinned" layer of tissue. Winston et al, however, teaches that it was known to thin tissue for similar devices such that the claimed thinned state is obvious as a way to improve the viability of the implant or to reduce the profile of the stent; see the abstract. Hence, it is the Examiner's position that it would have been obvious to use thinned tissue in the Love device for the same reasons that Winston et al uses the same.

Furthermore, the mere setting forth of a thickness is not considered sufficient to support patentability and would have been obvious to an ordinary artisan in the art; there is no criticality set forth or shown for the less than 0.45 mm thickness range claimed. In particular, MPEP 2144.04 is incorporated herein by reference and states:

> *In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.*

With regard to claim 29, since the support frame can be made of spring material, it is in a configuration and a condition to the compressed and expanded since the material is by nature springy or spring-like. The outer surface as claimed is the outer surface of the helical element or ring elements. The tissue is wrapped and overlapped over the helical element (16) such that is it configured to unwrap as the helical element is expanded.

With regard to claim 30, the terminology "about equal" is construed to be broad such that the overlapped tissue reads on it. Alternatively, such overlapping is considered to rendered obvious to the claim language calling for "about equal to the second circumference."

With regard to claim 36 specifically, Love teaches that it was known to have the inner and outer layers longer than the stent but not specifically by less than 5 % as claimed. However, since there is not criticality for this feature, it is the Examiner's position that it would have been prima facie obvious to match the length of the stent and tissue cover closely in order to reduce the cost of making the device and in order to prevent loose tissue ends from causing thrombosis of the vessel.

With regard to claim 41, the at least one securing member as claimed is met by the outer helical member (14) or the hooks, barbs, and staples of Love (WO).

With regard to 42, the claimed thickness is within the range of tissue 0.2 mm to 0.8 mm disclosed by Claeson for pericardial tissue, and for this reason, the Examiner asserts that the claimed range is inherently met by Love. Alternatively, the claimed range is considered prima facie obvious over Love (WO).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Love, Claeson, and Whitson as applied against claim 1 above and in further view of Narciso (WO 94/15583). Love fails to include a therapeutic material in the graft thereof. Narciso teaches that it was known to use therapeutic materials in similar implants. Hence, it is the Examiner's position that it would have been obvious to do the same for the same reasons that Narciso does the same.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Love (WO 97/24081), Claeson et al (US 6,468,313), and Winston (US 6,117,166) as set forth in the earlier rejection and in further view of Dereume (US 5,653,747). Love at least renders the claim language obvious as set forth in the rejection of claim 1 above, but Love fails to teach the concept of having the jacket shorter than the stent or support as claimed. Dereume, however, teaches that it was known to make the graft slightly shorter than the stent or support; see the figures. Therefore, it is the Examiner's position that it would have been obvious to make the support of Love longer than the tissue graft is supports for the same reasons that Dereume does the same in the invention thereof.

Response to Arguments

Applicant's arguments filed December 6, 2004 have been fully considered but they are not persuasive.

With regard to the traversal that Love does not teach thinned tissue, a graft less than 0.45 mm thick and the use of an expandable stent, the Examiner has addressed

these arguments in the newly presented rejections above. Applicants are directed to these rejections.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
Primary Examiner
Art Unit 3738